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COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			EXAMINER STOUT, MICHAEL C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,518	Applicant(s) DUNKER ET AL.	
	Examiner MICHAEL C. STOUT	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/532518 filed 25 April 2005 and is final action based on the merits of the application.

Claim Objections

1. Claim 1 is objected to because of the following informalities: Claim 1 recites a biopsy material holding device "wherein a wire with beveling..", wherein should be replaced with –comprising--. Appropriate correction is required.
2. Claim 6 is objected to because of the following informalities: Claim 6 recites a biopsy material holding device "wherein the wire..", should be replaced with –said wire--. Appropriate correction is required.
3. Claim 4 is objected to because of the following informalities: Claim 4 recites a biopsy material holding device "beveling... is facing the biopsy materially cylinder", should contain the phrasing "adapted to... face the cylinder". Appropriate correction is required.
4. Claim 7 is objected to because of the following informalities: Claim 7 recites a biopsy material holding device "the latter's", should be replaced with a reference to the biopsy cannula. Appropriate correction is required.
5. Claim 9 is objected to because of the following informalities: Claim 9 recites a biopsy material holding device "a pre-stress angel", should be replaced with "said pre-stress angle". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Regarding claim 1, at least the claimed recitation of "a wire with beveling arranged at the distal end of said wire at a biopsy material holding device has a pre-stress angle" is ambiguous because the statement comprises grammatical errors which make the structure of the device unclear.
8. Regarding Claims 2 and 3 which recite the limitation "a wire" which is previously claimed in claim 1 "a wire with beveling arranged at the distal end of said wire," and it is unclear whether the limitations refer to the previous wire or a new wire is being claimed.
9. Regarding Claim 4 which recite the limitation "a beveling" which is previously claimed in claim 1 "a wire with beveling arranged at the distal end of said wire," and it is unclear whether the limitations refer to the location of previously claimed beveling or a second beveling is being claimed.
10. Regarding Claim 4 which recites the limitation "the biopsy material cylinder" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

11. Regarding Claim 6 which recites the limitation "the grip end" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

12. Regarding Claim 7 which recites the limitation "a length that corresponds to that of the biopsy of the cannula". The claim is ambiguous because "to that" is an indefinite term it is unclear what part of cannula is being referred to.

13. Claim 8 recites the limitation "the grip end" in claim 1. There is insufficient antecedent basis for this limitation in the claim and it is unclear what the grip end is of (the grip end ... of what?). Claim 8 recites the limitation "the grip end of the biopsy cannula" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Further more, both terms the grip end which can make the claims unclear.

14. Claim 9 recites biopsy material holding device "a pre-stress angle", it is unclear whether the "a pre-stress angle" is referring to the previously claimed pre-stress angle in claim 1 or another pre-stress angle.

15. Claim 10 recites the limitation of "a known cannula" which is inconsistent with the terms used on the claims of "the biopsy cannula".

16. Claim 10 recites the limitation "the grip end" in claim 1. There is insufficient antecedent basis for this limitation in the claim and it is unclear what the grip end is of (the grip end ... of what?). Claim 8 recites the limitation "the grip end of the biopsy cannula" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Further more, both terms the grip end which can make the claims unclear.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Urie et al. (US 5,059,187).

Regarding claim 1, Urie discloses a device for a biopsy cannula to perform transcutaneous biopsies of tissue, in particular hard tissue and bone marrow tissue using a biopsy material holding device that can be inserted into the proximal end of a biopsy cannula (7, see Column 2, Lines 46-68) and is inserted between the inner wall of a biopsy cannula and the tissue-removing cylinder, wherein,

a wire (1) with beveling arranged at the distal end of said wire (the wire has a distal end best seen in Figure 3), “at” [examiner reads as: “in”] a biopsy material holding device and has a pre-stress angle (4) causing the wire to glide along the inner wall of the biopsy cannula when inserted into the biopsy cannula, a tip of the wire exerting a radial outward direction force on the inner wall of the biopsy cannula (see Column 2, Lines 46-68).

Regarding claim 2, Urie teaches the device wherein the wire with a pre-stress angle (4) is arranged at the center of the grip end (1, the bend 4 is arranged in the center axis of the grip end 1, best shown in Figure 3), with the pre-stress angle being

between 1° and 90° (See Also 11, and 12 in Figure 6, which shows a wire having pre-stress angles 11 and 12 arranged in the center portion of the grip portion of the shaft.

19. Claims 1, 2 and 4, 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Janese et al. (US 4,781,202).

Regarding claim 1, Janese discloses a biopsy material holding device for a biopsy cannula to perform transcutaneous biopsies of tissue, in particular hard tissue and bone marrow tissue using a biopsy material holding device that can be inserted into the proximal end of a biopsy cannula (26, see Figure 1) and is inserted between the inner wall of a biopsy cannula and the tissue-removing cylinder (see Abstract and best seen Figure 10), wherein,

a wire (19, best shown in Figure 2b) with beveling (25) arranged at the distal end of said wire, "at" [examiner reads as: "in"] a biopsy material holding device (see Figure 1) and has a pre-stress angle (23) causing the wire to glide along the inner wall of the biopsy cannula when inserted into the biopsy cannula, a tip of the wire exerting a radial outward direction force on the inner wall of the biopsy cannula (the pre-stress angle is a spring like bend when not restrained and is capable of being insted into a cannula and exerting a radial outward force generated by the natural bend in the wire on the inner wall of the cannula).

Regarding Claim 2, Janese further discloses the biopsy material holding device for a biopsy cannula according to claim 1, wherein the biopsy material holding device is made of a wire attached to a grip end (10, see Figure 2b).

Regarding Claim 4, Janese further discloses the biopsy material holding device for a biopsy cannula according to claim 1, wherein the wire has a tip with a beveling (best seen in Figures 2a and 2b) and the tip with beveling has a beveling angle B of 5° to 85° (best shown in Figures 2a and 2b) and is facing the biopsy material cylinder (best seen in Figures 7-10 which show the beveled surface facing the tissue).

Regarding Claim 6, Janese further discloses the biopsy material holding device for a biopsy cannula according to claim 1, wherein the wire with a pre-stress angle is arranged at the center of the grip end (Figure 2b shows the angle 23 is along the axis of the wire arranged in the center of the grip 10), with the pre-stress angle being between 1° and 90° (see Figure 2b).

Regarding Claim 7, Janese further discloses the biopsy material holding device for a biopsy cannula according to claim 1, wherein the wire has a length that corresponds to that of the biopsy cannula (best shown in Figures 1 and 2) and ends at the latter's ending (Figures 7-10 show the wire ending at the ending of the cannula 26).

Regarding Claim 8, Janese further discloses the biopsy material holding device for a biopsy cannula according to claim 1, wherein the grip end can be locked into the grip end of the biopsy cannula (Figure 1 shows the grip end (proximal end of the wire

comprising the handle 10) inside the cannula hub 12 which locks the preventing it from movement perpendicular to the long axis of the cannula 26).

1. Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Paolo et al. US Patent 5,910,121 (hereinafter Paolo).

Regarding Claim 1 Paolo teaches:

A biopsy material holding device (intermediate cannula) for a biopsy cannula to perform transcutaneous biopsies of tissue, in particular hard tissue and bone marrow tissue (see Technical Field, Column 1, Paragraph 1) using a biopsy material holding device that can be inserted into the proximal end of a biopsy cannula (see Summary of the Invention, Lines 49-54 and Column 2, last Paragraph) and is inserted between the inner wall of a biopsy cannula and the tissue-removing cylinder (see Figure 5), wherein, a wire (a resection means preferably a pair of thin plate 116 see Figure 5), which can reasonably be interpreted as a wire, made of a suitably elastic material in particular spring-steel, see Column 3, lines 1-5 and 43-46) with a bevelling (the plates 116 have pointed extensions 116b, see Figures 4 and 5) is arranged at the distal end of said wire, "at" [examiner reads as: "in"] a biopsy material holding device and the wire having a pre-stress angle (the pointed extensions 116b are bent in such a way as to close one against the other when the device is in non-operation condition, see Figure s 5 and 6 and Column 3 Lines 1,2,56-59) causing the wire to glide along the inner wall of the biopsy cannula when inserted into the biopsy cannula, a tip of the wire exerting a radial

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outward direction force on the inner wall of the biopsy cannula (the pre-stress angle is a spring like bend when not restrained and is capable of being inserted into a cannula and exerting a radial outward force generated by the natural bend in the wire on the inner wall of the cannula).

Regarding Claim 2 and 3, Paolo teaches he biopsy material holding device for a biopsy cannula according to claim 1 as set forth above wherein, the biopsy material holding device is made of a wire (6, see Figure 1, 5 and 6) attached to a grip end (a barrel like element 5 located in the handle 3). The wire is connected to the handle via the intermediate cannula, which is connected to the handle by means of a binding barrel like element 5, see Column 3 Lines 39-42 and Figure 1. Therefore, Paolo teaches a biopsy material holding device composed of a grip end with an attached extension shank (intermediate cannula 4) and that a wire (116) is fastened to the shank (see Figures 1, 4 and 5).

Regarding Claim 4 Paolo teaches the biopsy material holding device for a biopsy cannula according to claim 1 as set forth above wherein, the wire has a tip with a bevelling and the tip with bevelling has, a bevelling angle B of 5° to 85° , Figure 5 shows a wire 116 that has a beveled tip 116b with an angle visibly between 5° and 85° , and is facing the biopsy material cylinder (Figure 4 shows the upper part of the tip 6b facing the biopsy cylinder P).

Regarding Claim 6, Paolo teaches the biopsy material holding device for a biopsy cannula according to claim 1, wherein the wire with a pre-stress angle is arranged at the center of the grip end (as best seen in Figure 1 the wire is arranged in the center of the grip ends 5 and 3, the wire arranged along the an axis of the cannula which is arranged in the center of the grip ends), with the pre-stress angle being between 1° and 90° (Figures 5 and 6 shows the pre-stress angle of the wire 116 to be between 1° and 90°).

Regarding Claim 7, Paolo teaches the biopsy material holding device for a biopsy cannula according to claim 1, wherein the wire has a length (the wire 116 and 4 in Figures 1, 5 and 6 show the wire has a length) that corresponds to that of the biopsy cannula at ends at the latter's ending (as best seen in Figures 1, 2, and 5 show the wire dimensions corresponds to the cannula and ends at the distal tip).

Regarding claim 8 Paolo teaches:

A biopsy material holding device for a biopsy cannula (4)
according to claim 1 as set forth above -wherein,

the grip end can be locked into the grip end (the binding barrel like element 5 is fastened to the handle 3, see Column 3 Lines 42-43) of the biopsy cannula (2, see Figure 1).

Regarding Claim 9 Paolo teaches:

A biopsy material holding device for a biopsy cannula according to claim 3 as set forth above –wherein,
the wire (thin metal plate 116, see Figure 1) is firmly connected to the distal end of the shank (intermediate cannula 4, see Figures 1, 4 and 5) and a pre-stress angle between 1° and 90° is provided (Figures 5 and 6 shows the pre-stress angle of the wire 116 to be between 1° and 90°), according to the specific application.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paolo Janese in view of Fukuda et al. US Patent 6,322,581 B1 (hereinafter Fukuda).

Janese disclosed the device of claim 1 as set forth above. Janese fails to teach the device wherein, the bevelling of the wire is either hollow ground, also known as concave, or bulged, also commonly known as convex (hollow ground creates a concave bevel surface and a bulge bevel leaves a convex or bulge bevel surface).

Fukuda teaches a various bevel finishes known in the art, for a suturing needle (wire) for medical use. Figures 4a thru 4e shows the bevelling on needles (wire) that are either hollow ground (52, Figure 4c) or bulged (51a, Figure 4b).

Because both Janese and Fukuda teach wires having beveled surfaces, it would have been obvious to one having ordinary skill in the art to substitute one type of bevelling for another to achieve the predictable result of creating the tissue biopsy holding device taught by Janese with the wire having a hollow ground or bulged bevel surface in order to provide desired tissue interaction characteristics, see Fukuda Column 1, Line 48 through Column 2, Line 10 because when there is a design need or

market pressure to solve a problem and there are a number of identified, predictable solutions (providing a beveled surface), a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense.

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paolo et al. US Patent 5,910,121 (hereinafter Paolo) in view of Fukuda et al. US Patent 6,322,581 B1 (hereinafter Fukuda).

Paolo anticipates the biopsy material holding device according to Claim 1 as set forth above wherein the device has a wire with bevelling. Paolo fails to teach the device wherein, the bevelling of the wire is either hollow ground, also known as concave, or bulged, also commonly known as convex (hollow ground creates a concave bevel surface and a bulge bevel leaves a convex or bulge bevel surface).

Fukuda teaches a various bevel finishes known in the art, for a suturing needle (wire) for medical use. Figures 4a thru 4e shows the bevelling on needles (wire) that are either hollow ground (52, Figure 4c) or bulged (51a, Figure 4b).

Because both Paolo and Fukuda teach wires having beveled surfaces, it would have been obvious to one having ordinary skill in the art to substitute one type of bevelling for another to achieve the predictable result of creating the tissue biopsy holding device taught by Paolo with the wire having a hollow ground or bulged bevel

surface in order to provide desired tissue interaction characteristics, see Fukuda Column 1, Line 48 through Column 2, Line 10 because when there is a design need or market pressure to solve a problem and there are a number of identified, predictable solutions (providing a beveled surface), a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense.

24. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paolo in view of Janese.

Paolo teaches the device of claim 3 as set forth above wherein the wire has a length (see Figure 5) and ends at the end of a biopsy cannula (best shown in Figure 1) after insertion of the shank and locking of the grip end into the grip end of the biopsy cannula (Column 3 Lines 37-42 and shown in Figure 1).

Paolo fails to teach the device wherein the length of the wire is 25mm.

The matter of providing a wire with a length of 25mm is an obvious matter of design choice involving the change of size of a component, see MPEP 2144.04

The obvious matter of a design choice is supported by Janese which teaches a biopsy holding device comprising a wire having a bend section wherein the length of the angle to the tip is approximately 13mm and teaches that the size and length of the components can be varied depending on the application, see Column 4, Lines 4-17 and Column 5, Lines 10-36).

Thus it would have been obvious to a person of ordinary skill in the art to modify the device taught by Paolo to have a wire length of 25mm in order to provide a appropriately dimensioned device for a given application as taught by Jenese wherein the only difference is the relative size and has not different function from the prior art.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Response to Arguments

The Applicant's amendment(s), see Response, filed 1/22/2008, with respect to specification overcomes the previous objections. The objections of specification have been withdrawn.

The Applicant's amendment(s), see Response, filed 1/22/2008, with respect to drawings overcomes the previous objections. The objections of drawings have been withdrawn.

The Applicant's amendment(s), see Response, filed 1/22/2008, with respect to claims overcomes the previous objections. The objections to the claims from the preceding office action dated 9/17/2008 have been withdrawn.

Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues that the amended claim 1 recites the limitation "a wire with beveling arranged at the distal end of the wire at a biopsy holding device has a pre-stress angle causing the wire to glide along the inner wall of the biopsy cannula when inserted into the biopsy cannula, with the tip of the wire exerting a radial outward directed force on the inner wall of the biopsy cannula," which is not taught by the prior art.

These limitations have been addressed in the above office action.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736